

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

In re:)	MDL No. 1456
)	Civil Action No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY)	Subcategory No. 06-11337
AVERAGE WHOLESALE PRICE)	
LITIGATION)	Hon. Patti B. Saris
_____)	

THIS DOCUMENT RELATES TO:

<i>United States ex rel. Ven-A-Care of the</i>)
<i>Florida Keys, Inc. v. Schering Corporation,</i>)
<i>Schering-Plough Corporation and</i>)
<i>Warrick Pharmaceuticals Corporation</i>)
Civil Action No. 09-CV-10547)
MDL Action No. 1456)
)
<i>United States ex rel. Ven-A-Care of the</i>)
<i>Florida Keys, Inc. v. Schering Corporation,</i>)
<i>Schering-Plough Corporation and</i>)
<i>Warrick Pharmaceuticals Corporation</i>)
Civil Action No. 00-CV-10698)
MDL Action No. 1456)
)
<i>California ex rel. Ven-A-Care of the</i>)
<i>Florida Keys, Inc. v. Schering Corporation,</i>)
<i>Schering-Plough Corporation and</i>)
<i>Warrick Pharmaceuticals Corporation</i>)
Civil Action No. 03-CV-11226)
MDL Action No. 1456)

**RESPONSE BY SCHERING-PLOUGH CORPORATION, SCHERING CORPORATION,
AND WARRICK PHARMACEUTICALS TO MASSACHUSETTS' SUR-REPLY AND
SUPPLEMENTAL SUR-REPLY IN OPPOSITION TO THE PARTIES' JOINT MOTION
FOR THE APPROVAL OF THE SETTLEMENT WITH CALIFORNIA, FLORIDA, AND
RELATOR VEN-A-CARE OF THE FLORIDA KEYS**

On August 7, 2009, California, Florida, and the Relator Ven-A-Care of the Florida Keys, Inc. (“Ven-A-Care”), together with Schering-Plough Corporation, Schering Corporation, and Warrick Pharmaceuticals Corporation (collectively, “Schering/Warrick” and, together with California, Florida, and Ven-A-Care, the “Settling Parties”) jointly moved this Court for approval of their proposed settlement and the dismissal with prejudice of, *inter alia*, the above-captioned cases. *See* Jt. Mot. for Approval of the Settlement between California, Florida, and Relator Ven-A-Care of the Florida Keys on behalf of Itself and the United States and Schering-Plough, Schering, and Warrick (Dkt. 6359). The United States and certain state and local governments opposed the motion. The Settling Parties subsequently agreed to revise their proposed settlement to address the objections of the United States, which now has agreed to consent to the current version of the proposed settlement and to the entry of the proposed order dismissing the above-captioned actions with prejudice. *See* Consent of the United States of America.

The Court has scheduled a Final Settlement Approval Hearing for December 11, 2009, at 3:00 p.m. At that hearing, the Settling Parties will request the entry of the proposed Order of Dismissal with Prejudice, a copy of which is attached hereto as Exhibit A. Although some of the terms of the proposed settlement have changed, the basic structure and effect of the settlement remain the same – to fully and finally resolve all claims with respect to the “federal-share” of any alleged Medicaid overpayments by Schering and Warrick. Presumably any objections by the state and local governments to the settlement – to the extent that they remain – will also be unchanged. Thus, with one exception, the issues presented by the objections have been fully briefed. In its Sur-Reply brief, and again in its Supplement Sur-Reply brief, Massachusetts raised for the first time an argument concerning the preclusive effect of the proposed settlement.

Schering/Warrick have not had an opportunity to respond to this argument, and now submit this memorandum to do so.

PRELIMINARY STATEMENT

In its Sur-Reply, and again in its Supplemental Sur-Reply, Massachusetts argues that the intended effect of the proposed settlement – to preclude litigation of any claims for the federal-share of any alleged Medicaid overpayment – is contrary to law. Instead, Massachusetts makes the novel assertion that any amount that Schering/Warrick pay to the United States constitutes nothing more than an offset to Massachusetts’ claim for the federal-share of all alleged Medicaid damages. This extraordinary argument is contrary to controlling United States Supreme Court and First Circuit precedent, and if adopted would effectively confer on states a *de facto* “veto right” over any federal False Claims Act settlement related to a jointly-funded federal/state program. Indeed, extended to its logical conclusion, Massachusetts would reserve to itself the right to continue to litigate a claim for the federal-share of alleged overpayments, or to assert a claim for the first time, even after the entry of a final judgment on the merits in an action by the United States, or a relator on its behalf, under the False Claims Act. Not surprisingly, there is no case law supporting the Massachusetts argument, and the edifice of the law of claim preclusion is arrayed against it. For the reasons set forth below, this Court should reject the Massachusetts argument as wholly unfounded and enter the proposed Order of Dismissal with Prejudice that the Parties have jointly submitted with the consent of the United States.

ARGUMENT

I. THE PROPOSED SETTLEMENT PROPERLY BARS THE COMMONWEALTH UNDER BASIC CLAIM PRECLUSION PRINCIPLES FROM CONTINUING TO LITIGATE CLAIMS FOR THE FEDERAL-SHARE OF MEDICAID REIMBURSEMENTS.

A. When Two Actions Assert a Claim for the Same Recovery, Final Judgment Rendered in the First Action to Reach Judgment Is Preclusive in the Other Action.

The analysis of this issue begins with the very basic and (presumably) non-controversial proposition that, “when two actions are pending which are based on the same claim, or which involve the same issue, it is the final judgment first rendered in one of the actions which becomes conclusive in the other action.” Restatement (Second) of Judgments § 14, cmt. A (1982). This proposition is squarely grounded in First Circuit precedent. *See, e.g., Giragosian v. Ryan*, 547 F.3d 59, 63-64 (1st Cir. 2008) (quoting the Restatement and collecting supporting authority from other circuits).¹ In the absence of this widely acceptable principle, the finality of the first judgment would be completely undermined and the possibility for the waste of judicial resources would be limitless. *Giragosian*, 547 F.3d at 64 (recognizing these consequences).²

There can be no question that Ven-A-Care (on behalf of the United States) and Massachusetts seek the same recovery in separate actions. Both actions seek to recover the federal-share of any alleged Medicaid overpayment for three Warrick albuterol products based

¹ Massachusetts’ Sur-Reply notes that *Giragosian* applied the “Massachusetts law of *res judicata*” and that the “preclusive effect of a federal court judgment is determined by federal common law.” (Massachusetts’ Sur-Reply at 5-6.) This argument misses the point as the First Circuit has found that “both Massachusetts law and federal common law apply the same analytical factors in deciding claim preclusion questions.” *Herman v. Meiselman*, 541 F.3d 59, 62 n.6 (1st Cir. 2008).

² In an analogous context to this one, the Second Circuit affirmed the district court’s injunction barring 31 states from bringing state law causes of action on behalf of their citizens against broker-dealers who had previously settled an MDL class action arising out of the same alleged misconduct and explaining, “no defendant in the consolidated federal actions in the present case could reasonably be expected to consummate a settlement of those claims if claims could be reasserted under state laws, whether by states on behalf of the plaintiffs or by anyone else seeking recovery of money to be paid to the plaintiffs.” *In re Baldwin-United Corp.*, 770 F.2d 328, 336-37 (2d Cir. 1985).

on the very same Medicaid claims submitted by pharmacists to the Massachusetts Medicaid program. It is true that the Massachusetts action also seeks to recover the “state-share” of the alleged overpayments, but the proposed settlement and release does not preclude Massachusetts or any other state from pursuing the claims that they make for the state-share of any alleged Medicaid overpayment. Rather, the settlement and release simply seeks to achieve finality as to claims for the federal-share.

In the First Circuit, the standard for determining whether claim preclusion applies in a subsequent action is: where a final judgment has been entered disposing of a claim that is also presented in a second action, the claim in the remaining action will be precluded if the two actions seek recovery based upon the “same transaction” or arise out of a common “nucleus of operative facts.”³ *Herman*, 541 F.3d at 62-63. Clearly, the transactions and the alleged conduct underlying the competing claims for the federal-share are the same in the Ven-A-Care and the Massachusetts actions. Similarly, as Schering/Warrick have pointed out, *see, e.g.*, Joint Mem. In Support of Jt. Mot. for Approval of the Settlement between California, Florida, and Relator Ven-A-Care of the Florida Keys on behalf of Itself and the United States and Schering-Plough, Schering, and Warrick (Dkt. 6364), a dismissal with prejudice entered pursuant to the terms of a settlement agreement will constitute a final judgment on the merits for purposes of claim preclusion. *Larken, Inc. v. Wray*, 189 F.3d 729, 732 (8th Cir. 1999) (collecting cases); *see also Nottingham Partners v. Trans-Lux Corp.*, 925 F.2d 29, 31-32 (1st Cir. 1991) (finding that a settlement and release of claims bars a suit in either of two ways: by operation if the doctrine of *res judicata* or by proof of release of the claims). Thus, the only open question is whether

³ There is no disagreement between Schering/Warrick and Massachusetts as to the elements of claim preclusion. As the Commonwealth points out in its brief, *see* Massachusetts’ Sur-Reply at 5, claim preclusion requires a showing of three basic elements: (1) a final judgment on the merits; (2) disputes arising out of the same transaction or occurrence (or a “common nucleus of operative facts”); and (3) a sufficient identity of the parties that preclusion is warranted against the party against whom preclusion is sought. *See Herman*, 541 F.3d at 62.

Massachusetts, which is not a party to this action, can be bound by a final judgment entered in this case. As explained in Section B below, the answer to that question is a resounding “yes.”

B. The United States Supreme Court’s Recent Decision In *Taylor v. Sturgell*, and Prior Rulings by this Court in this AWP MDL, Make Plain that Claim Preclusion Applies Here Even Absent an Identity of the Parties.

The United States Supreme Court reiterated as recently as its 2008 Term that the doctrine of claim preclusion can apply to a non-party, such as Massachusetts, in at least “six established categories” of circumstances: (1) where a non-party has agreed to be bound by the determination of the issues in an action between others; (2) where a “pre-existing substantive legal relationship” exists between the person to be bound and a party to the judgment; (3) where a non-party was “adequately represented” by someone with the same interests who was a party to the suit; (4) where a non-party assumed control over the litigation in which that judgment was rendered; (5) where a non-party is a “proxy” or “designated representative” of a person who was a party to the prior litigation; and (6) where a “special statutory scheme” expressly forecloses successive litigation by non-parties. *Taylor v. Sturgell*, ___ U.S. ___, 128 S.Ct. 2161, 2172-73 (2008). At least three of these “established categories” apply in this case.

First, this Court’s recent discussion of the joint state/federal nature of the Medicaid program and its operations in *United States ex rel. Ven-A-Care of the Florida Keys v. Actavis Mid Atlantic LLC*, ___ F.Supp. 2d ___, 2009 WL 3171798 (D. Mass. Oct. 2, 2009), leaves no room for doubt that a “pre-existing substantive legal relationship” exists that precludes states, such as Massachusetts, from recovering the federal-share of any alleged Medicaid overpayment resolved as a part of this settlement. In relevant part, this Court explained:

Medicaid is based upon a comprehensive funding and reimbursement structure between the state and federal government . . . Medicaid is not funded by a static block grant. Instead, the state seeks federal funding through quarterly requests, draws down from federal letters of credit as

providers seek payment for Medicaid claims, and then submits reconciliations to the federal government which affect future funding. Under this funding scheme, in which false claims lead to direct draw downs from federal letters of credit, a provider who submits a false Medicaid claim to the state presents a false claim for payment or approval to the United States.

Id. at *6 (internal citations omitted). Thus, the federal-share of Medicaid funding is carefully controlled by the federal government, disbursed to the states only in response to provider claims, and comes with regulatory conditions that are binding on the states (including the obligation to seek recovery of overpayments for the benefit of the federal government). Certainly, it follows that if the same claims that are presented to a state Medicaid program are sufficient to give rise to liability to the federal government for the federal-share of any alleged Medicaid overpayment, then a settlement of such claims by the United States (and their dismissal with prejudice) should be sufficient to preclude a state from subsequently seeking the federal-share (again) based on the very same claims. Properly understood, therefore, the Medicaid reimbursement scheme plainly creates a “pre-existing substantive legal relationship” that bars re-litigation as to claims for the federal-share by states in subsequent proceedings.⁴

Second, the Supreme Court’s decision in *Taylor v. Sturgell* confirms that “a nonparty may be bound by a judgment because she was ‘adequately represented by someone with the same interests who [wa]s a party’ to the suit.” *Taylor*, 128 S.Ct. at 2172 (citing *Richards v. Jefferson County*, 517 U.S. 793, 798 (1996)). In this case, the United States’ interests were represented by a relator who was not only statutorily-empowered, but financially incentivized to

⁴ The application of preclusion principles is particularly compelling where the competing claimants are separate government entities. Indeed, the Court acknowledged in *Taylor* that this category of exception giving rise to non-party preclusion originates as much from property law as “from the values of preclusion by judgment,” which have special resonance in their application to claims presented in separate actions by different government entities. *Taylor*, 128 S. Ct. at 2172 (citing 18A Charles Alan Wright, Arthur R. Miller, & Edward H. Cooper, Federal Practice and Procedure § 4448 (3d ed. 2009) (hereinafter Wright & Miller) (noting a “wide array of problems that arise from successive litigation involving different government bodies”)); *see also* Wright & Miller § 4458 & n.7 (citing successive litigation regarding environmental protection claims as one example where preclusion applies to bar successive state or federal actions).

represent its interests. *See* 31 U.S.C. § 3730(b)(1) (authorizing actions by private citizens) *and* 31 U.S.C. § 3730(d) (awarding them a portion of any recovery). Indeed, Supreme Court precedent recognizes that a relator has Article III standing to bring claims on behalf of the United States under the federal False Claims Act as the legal *assignee* of the United States' claims. *Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 773 (2000); *see also United States ex rel. Barajas v. Northrop Corp.*, 147 F.3d 905, 910 (9th Cir. 1999). *Taylor v. Sturgell* expressly recognizes the “assignee” relationship as one of the “[q]ualifying relationships” included within this “established” category of non-party preclusion. *Taylor*, 128 S.Ct. at 2172.

Ven-A-Care has the “same interest” as Massachusetts in recovering the federal-share for the United States because each of them is obliged to vigorously pursue recovery of the same alleged overpayments on behalf of the same real party in interest, the United States. *See Vermont Agency of Natural Res.*, 529 U.S. at 773; SHO#08-004, Letter from Herb B. Kuhn, Acting Director, Center for Medicaid and State Operations, to all State Health Officials (Oct. 28, 2008), *available at* <http://www.nasmd.org/Home/Doc/SO08004.pdf> (the National Association for State Medicaid Directors website) (requiring states to pursue both the state- and federal-shares of any alleged Medicaid overpayments). It follows, therefore, that Massachusetts should be bound by this Court’s judgment even though it is a non-party to this suit. Moreover, as a very practical matter, the United States has – at all times – had the statutory right to intervene for good cause shown and to represent its own interests directly, which it effectively did in this case by objecting to the version of this settlement that was first proposed. *See* 31 U.S.C. §3730(c)(3) (“[T]he court . . . may nevertheless permit the government to intervene at a later date upon a showing of good cause.”). Again, under these circumstances, there can be little doubt that, even

though Massachusetts is a non-party, its “interests” in recovering the federal-share of any alleged Medicaid overpayment *on behalf of the federal government* were adequately protected in this lawsuit, such that it should be bound – particularly given that Massachusetts (1) would be required to refund the money that it recovered for the federal-share to the United States, *see* 42 U.S.C. § 1396b(d) (requiring that federal Medicaid funds to be paid to the state be reduced by any overpayment), and (2) the United States – the real party in interest – consents to this settlement and the dismissal with prejudice of “all claims related to the federal-share (defined to mean that portion of Medicaid expenditures paid by the United States) of any Medicaid overpayment allegedly arising out of the Covered Conduct (as defined in the Parties’ Settlement Agreement and Release) or the price reporting for reimbursement purposes for the Covered Drugs, including but not limited to the federal-share of any claim brought by a state arising out of or related to the Covered Conduct or the price reporting for reimbursement purposes for Covered Drugs.” *See* Consent of the United States of America (incorporating by reference and consenting to the entry of the proposed Order of Dismissal with Prejudice).

Third, as the Supreme Court recognized in *Taylor*, “a party bound by a judgment may not avoid its preclusive force by relitigating through a proxy” – in this case the states. *Taylor*, 128 S.Ct. at 2173. “Preclusion is thus in order when a person who did not participate in a litigation later brings suit as the designated representative of a person who was a party to the prior adjudication.” *Id.* Massachusetts, or any other state bringing a claim for the federal-share of any alleged Medicaid overpayment, does so as the “designated representative” of the United States, *see* 42 U.S.C. § 1396b(d)(2)-(3) (requiring states to sue for both the state- and federal-shares); *accord* SHO#08-004, *supra*, and is required – by statute – to return a portion of the recovery (*i.e.*, the so-called federal-share) to the United States. *Id.* at § 1396b(d). Under these

circumstances, Massachusetts, or any other state bringing a claim for the federal-share, must be considered a “proxy” for the United States and be bound by the terms of the dismissal order in this case under the Supreme Court’s precedent in *Taylor v. Sturgell*.

C. Massachusetts’ Other Preclusion Arguments Are Equally Without Merit.

The assertion that the Commonwealth makes in its previous filings – that, “[t]he law is clear that without an identity of plaintiffs, or a basis to find that the Commonwealth is in privity with the United States or the relator, there is no basis to find claim preclusion here,” *see* Supp. Sur-Reply at 2-3 (Dkt. 6565) – is just flat wrong. “A unanimous Supreme Court” did **NOT**, as the Commonwealth argues, reject “an attempt to expand claim preclusion to non-parties” last term. *Id.* at 3. To the contrary, while the Supreme Court rejected the broad notion of “virtual representation,” it held that, “[t]hough hardly in doubt, the rule against nonparty preclusion is subject to exceptions. For present purposes, the recognized exceptions can be grouped into six categories.” *Taylor*, 128 S.Ct. at 2172. As discussed above, at least three of those “established categories” recognized in *Taylor* apply in this case.⁵

Similarly, the provision in the Deficit Reduction Act of 2005 (“DRA”) to which Massachusetts cites does not overcome the application of the basic claim preclusion principles that bar continued litigation of the federal-share by the Commonwealth. *See* 42 U.S.C. § 1396h(a) (cited by the Commonwealth in its Opposition at 4 (Dkt. 6457)). While the DRA creates an incentive for states to adopt a state false claims act by allowing them to keep ten percent of a federal-share recovery, the provision does not fundamentally change the “pre-existing substantive legal relationship” that exists between the federal government and states

⁵ While the fourth exception recognized by the Court in *Taylor* may require a showing that “the nonparty vicariously participates in the litigation by exerting ‘substantial control’ over the prosecution or defense of the case,” *see* Supp. Reply at 7 (Dkt. 6503) and the case cited therein, such a showing is not required to satisfy several of the other exceptions recognized by *Taylor* and, accordingly, the lack of such a showing is not fatal to Schering/Warrick’s position as the Commonwealth contends. *See id.*

with respect to the federal-share of alleged Medicaid damages. In a statutory regime that already provides a statutory share to relators who pursue claims, the DRA simply expands the potential recipients of a statutory share to include states that conform their enforcement regimes to federal policy. There is nothing in the DRA that purports to alter the character of the claims by the states for the federal-share damages associated with any false claims, and such claims continue to be asserted by states on behalf of the federal government. Similarly, nothing in the DRA alters the right of the real party in interest – the United States – to control the disposition of the federal-share portion of any claim.

Moreover, in enacting the current version of the federal False Claims Act, Congress expressly considered and rejected the prospect that the alternative remedies provision of the False Claim Act might afford the United States itself “two bites at the apple” – one under the federal FCA and the other through an administrative proceeding or separate judicial action, such as the action pursued in Massachusetts’ own AWP case. *See, e.g.*, S. REP. NO. 99-345, at 27 (1986) (“While the Government will have the opportunity to elect its remedy, it will not have an opportunity for dual recovery on the same claim or claims. In other words, the Government must elect to pursue the false claims action either judicially or administratively and if the Government declines to intervene in a qui tam action, it is estopped from pursuing the same action administratively or in a separate judicial action.”); H.R. REP. NO. 99-660, at 24 (1986) (“However, the Committee does not intend that a person alleged to have violated the Act, be forced to defend himself in two forums at one time.”). Given Congress’s express intent against such a result, it is unimaginable that, by reallocating the potential recovery of the federal-share of any alleged Medicaid overpayment between the state and federal government in the DRA, Congress thereby created the prospect for double-recovery through claims by states. Allocation

of the federal-share is an issue entirely between the United States and the states and not involving Schering/Warrick, and should not have any bearing on the preclusive effect of a settlement of the United States' rights.

II. THE COMMONWEALTH'S RELIANCE ON *UNITED STATES* v. *BORNSTEIN* FOR ITS "OFFSET" ARGUMENT IS MISPLACED.

The *only* case that the Commonwealth cites in support of its "offset" argument, *United States v. Bornstein*, 423 U.S. 303 (1976), is entirely beside the point. *Bornstein* addressed the proper treatment of a prior recovery from a joint-tortfeasor when assessing double damages against another of the joint-tortfeasors. *Id.* at 313-17. At issue here is the question of the preclusive effect of a final judgment on claims seeking the exact same recovery from the exact same party – twice. There is only one alleged "bad actor" here – Schering/Warrick – and no allegation of joint and several liability. Accordingly, *Bornstein* has absolutely no bearing on the issue of the preclusive effect of this settlement. As noted above, the First Circuit's decision in *Giragosian v. Ryan*, 547 F.3d 59 (1st Cir. 2008), taken together with the Supreme Court's decision in *Taylor v. Sturgell*, 128 S.Ct. at 2161, controls the question here.

CONCLUSION

For all of these reasons, and for the reasons set forth the Settling Parties' various memoranda in support of their Joint Motion for the Approval of the Settlement, the Settling Parties respectfully request that the Court consent in writing to their proposed settlement and enter the proposed Order of Dismissal with Prejudice of Schering-Plough Corporation, Schering Corporation, and Warrick Pharmaceuticals Corporation, a copy of which is attached hereto as Exhibit A.

Respectfully submitted,

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Dated: December 7, 2009

CERTIFICATE OF SERVICE

I hereby certify that on December 7, 2009, a true copy of the above Joint Motion was served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

December 7, 2009

/s/ John P. Bueker
John P. Bueker